03-SAR-096

INDIANA UNIVERSITY

FACSIMILE TRANSMITTAL SHEET

RESEARCH AND THE UNIVERSITY GRADUATE SCHOOL

TO: Select Agent Program FROM: Jeffrey R. Alberts

COMPANY: Centers for Disease Control and Prevention DATE: 02/11/03

FAX NUMBER: 404-498-2265 TOTAL NO. OF PAGES, 5

PHONE NUMBER: 404-498-2255

REGARDING:
Indiana University - Bloomington Comments on HHS's Interim Final Rule on the Possession, Use and Transfer of Select Agents and Toxins

☐ URGENT ☐ FOR REVIEW ☐ PLEASE REPLY ☐ PLEASE ACKNOWLEDGE

COMMENTS:

Indiana University - Bloomington Comments on HHS's Interim Final Rule on the Possession, Use and Transfer of Select Agents and Toxins

OFFICE OF THE VICE PRESIDENT AND DEAN

Bryan Hall 104
Bloomington, Indiana
47405-1201

812-855-8913
Fax: 812-855-2205

INDIANA UNIVERSITY

RECEIVED FEB 11 2003

5 February 2003

Indiana University - Bloomington Comments on HHS's Interim Final Rule on the Possession, Use and Transfer of Select Agents and Toxins

(67 FR 76886-76905)

RESEARCH AND THE UNIVERSITY GRADUATE SCHOOL

Select Agent Program
Centers for Disease Control and Prevention
1600 Clifton Rd., E-70
Atlanta, GA 30333

Dear Select Agent Program,

The Indiana University, Bloomington (University) submits the following comments on U.S. Department of Health and Human Services' (HHS) Interim Final Rule on the Possession, Use and Transfer of Select Agents and Toxins. The interim rule was published in the 13 December 2002 *Federal Register* (67 FR 76886-76905). As the University is a leading educational institution with more than $100 Million in annual external research funding, we believe that our information and suggestions may be valuable to HHS. The University is registered under the current select agent rule (Section 72.6 of Title 42 of the Code of Federal Regulations).

WELCOME PROVISIONS OF THE INTERIM RULE

We support the following provisions of 42 CFR 73:

- We appreciate that required Safety and Security Plans are largely performance-based. 42 CFR 73 establishes performance standards and allows Entities to create individual plans to meet those standards. We appreciate that the Security requirements of Section 73.11 do not prescribe card access, video surveillance or other specific technologies. Performance-based regulations are most efficient and effective because they allow each Entity to adopt the best compliance methods for its own circumstances and institutional organization. Subsequent changes or additions to the rules should maintain and improve their performance basis.
- We believe the exclusion amounts for toxins in 73.4(f)(4) and 73.5(f)(4) are reasonable and protective of human health and the environment.
- We appreciate that quantity records are only required for toxins under 73.15(b)(2), (5) and (7). It is not practical to quantify viable agents.

DEFINITIONS

Recommendation: 42 CFR 73 should include a definition of "access" to mean: "The ability to gain physical control of select agents and toxins."

OFFICE OF THE VICE PRESIDENT AND DEAN

Bryan Hall 104
Bloomington, Indiana
47405-1201

812 855 8913
Fax: 812-855-2205

The rules are confusing because the word, "access" is used several times with different meanings. We agree with comments made by the Howard Hughes Medical Institution (HHMI) that the above definition of "access" would minimize uncertainty and help Entities comply with the security, training, and record keeping requirements

INDIANA UNIVERSITY

RESEARCH AND THE UNIVERSITY GRADUATE SCHOOL

that rely on "access." The recommended definition would apply to those sections of 42 CFR 73 where "access to a select agent," "access to containers," or "approved for access" are used.

We also agree with HHMI that the term "entry" should replace "access" when a requirement addresses admission to a select agent area by an individual not approved under 73.8. Specifically, "entry" should replace "access" in Sections 73.11(b)(6), 73.13(c) and (e), and 73.14(c)(2). These changes and the above definition would greatly clarify the rules.

Recommendation: Clarify that Entities have discretion to define "area" in their security plans.

Entities should have the discretion to define "area" because the appropriate security measures will vary for each location, circumstance and institution. By defining "area" in their security plans, Entities will clearly specify the physical limits of their security measures. A specific delineation of "area" will aid Entities, investigators and inspectors in complying with the rules.

SELECT AGENTS AND TOXINS

Recommendation: Clarify 42 CFR 73.4(e)(1) and 73.5(e)(1) to include genetic elements and recombinant organisms that can encode infectious and/or replication competent forms of any of the select agent viruses.

We appreciate your consideration of the University's 12 September 2002 comments to exclude genetically modified microorganisms that do not encode for any virulence factors or toxins and are unable to propagate. 42 CFR 73.4(e)(1) and 73.5(e)(1) states that "nucleic acids...that can encode infectious and/or replication competent forms of any of the select agent viruses." are covered by the regulations, which thereby excludes replication-incompetent forms. Our recommendation would clarify that this exclusion logically extends to replication- incompetent genetic elements and replication-incompetent recombinant organisms.

HHS EXCLUSION DETERMINATIONS

Recommendation: Make prompt determinations on applications for exclusions under 42 CFR 73.4(f)(5).

42 CFR 73.4 regulates vaccine strains, genetic elements and other agents currently exempt under 42 CFR 72, or individual exemptions granted under 42 CFR 72. CDC granted additional exemptions under 42 CFR 72 on a case-by-case basis. Many of these exemptions continue to have merit. Entities have applied (and will apply) for an exclusion under 42 CFR 73.4(f)(5). Delays in making these determinations will result in the expenditure of considerable funds and resources to comply with 42 CFR 73 requirements. These delays may also interrupt or delay important research. We urge HHS to give priority to consideration of exclusion applications.

OFFICE OF THE VICE PRESIDENT AND DEAN

Bryan Hall 104
Bloomington, Indiana
47405-1701

812-855-8913
Fax: 812-855-2205

COMPLIANCE SCHEDULES FOR NEW RESEARCHERS

INDIANA UNIVERSITY

RESEARCH AND THE UNIVERSITY GRADUATE SCHOOL

OFFICE OF THE VICE PRESIDENT AND DEAN

Bryan Hall 104
107 Indiana Avenue
Bloomington, Indiana
47405-7000

812-855-8913
Fax: 812-855-6396

Recommendation: Clarify the security risk assessment compliance schedule for new individuals needing access to select agents between 11 June 2003 and 11 November 2003.

Section 73.0(a) and (b) provides the compliance schedules for Entities that on 7 February 2003 already were conducting activities under a certificate of registration issued under 42 CFR 72.6. However, security risk assessment procedures and work restrictions are not clear for select agent researchers who begin work for a currently registered Entity between 11 June 2003 and 11 November 2003. For example, a new researcher who wishes to begin select agent work for a registered Entity during that period is not subject to 73.0(b)(3). This appears to contradict 73.0(a)(4). Please explain.

SECURITY RISK ASSESSMENT FOR UNIVERSITY OFFICIALS

Recommendation: Clarify that, at a state university, security risk assessments are required only of the Responsible Official, Alternative Responsible Official, and individuals who access a select agent or toxin.

73.8(a) does not apply to state agencies. Public universities are owned and controlled by the citizens of the state and their elected officials. As a result, security risk assessments at universities considered to be state agencies should be required of only of the Responsible Official, Alternative Responsible Official, and individuals who access a select agent or toxin.

RESPONSIBLE OFFICIAL

Recommendation: Clarify that a Responsible Official may receive the transfer of a select agent or toxin for the purposes of ensuring institutional compliance.

The rule's preamble recommends that the Responsible Official be a biological safety officer but not be someone who receives select agents. We understand the safeguard of not designating a select agent user as the Entity's Responsible Official. However, receipt of select agents and toxins by the Responsible Official is a valuable procedural control to ensure that all required compliance measures are in place prior to final delivery of the agent to the Investigator. After passage of the USA Patriot Act, the University revised its procedure to require that all shipments of select agents be received by its Department of Environment Health, and Safety, whose director has been designated as our Responsible Official. This procedure parallels the common and effective practice of requiring receipt of radionuclides by the Radiation Safety Officer prior to their distribution to the Principal Investigator.

SECURITY

Recommendation: Clarify that 73.11(d)(4) only applies to packages used for the shipment or transfer of select agents or toxins. Also, clarify who should perform these inspections.

It is not practical to inspect the many packages of laboratory supplies, autoclaved waste, etc. that enter and exit the select agent laboratory every day.
If 73.11(d)(4) applies only to packages used for the shipment or transfer of select agents or toxins, these inspections should be performed by the Responsible Official or the Alternate Responsible Official.

INDIANA UNIVERSITY

RESEARCH AND THE UNIVERSITY GRADUATE SCHOOL

TRAINING

Recommendation: Clarify 73.13(a) by stating that, while training need not duplicate training provided under the OSHA Bloodborne Pathogen Standard 29 CFR 1910.1030, safety and security training is appropriate for individuals with access to select agents.

Section 73.13(a) implies that an Entity covered by the OSHA Bloodborne Pathogen Standard is not required to provide information and training on safety and security. We appreciate HHS's interest in avoiding unnecessary duplicative training. However, an Entity covered by the OSHA Bloodborne Pathogen Standard may have individuals who work in or visit areas containing select agents and toxins who are not covered by the standard themselves. Moreover, safety and security training is appropriate for all individuals with access to select agents.

COSTS OF IMPLEMENTING THE INTERIM FINAL RULE

The Interim Rule grossly underestimates the cost burden of implementing these new requirements. Contrary to the preamble, 42 CFR 73 implementation will require significantly more resources than compliance with *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*. In addition to new staff and recordkeeping requirements, the full cost of implementing this rule will not be known until HHS reviews and approves of individual safety and security plans. Improvements would reasonably include expanding electronic card access, alarm systems and security cameras, all of which are suggested in the rule. At Indiana University - Bloomington, we estimate that these additional security measures would cost hundreds of thousands of dollars, further stressing our budgets which have been ravaged by non-funded mandates concerning regulation and compliance.

CONCLUSION

In conclusion, the University supports the performance-based aspects of these Interim Rules for select agents and toxins. Although the University's select agent activities are very limited, select agents compliance requires the expenditure of significant University resources. We hope that consideration of our comments will facilitate efficient and effective compliance with these new rules.
Thank you for the opportunity to comment on this proposal and for considering our comments. Should you have questions after you've had an opportunity to review this letter, please contact me, or Ann Gellis, Associate Dean for Research Compliance at (812) 855-8914.

Sincerely,

Jeffrey R. Alberts
Professor of Psychology and
Associate Vice President for Research

OFFICE OF THE VICE PRESIDENT AND DEAN

Bryan Hall 104
Bloomington, Indiana
47405-1201

812-855-8913
Fax: 812-855-2205